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DW

08/851,628

APPLICATION NO. <i>08/851,628</i>	FILING DATE <i>05/04/97</i>	FIRST NAMED INVENTOR <i>COHEN</i>	ATTORNEY DOCKET NO. <i>C</i> <i>CRP-145</i>
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HM22/0512

EXAMINER <i>ROMEO, D</i>

ART UNIT <i>1646</i>	PAPER NUMBER <i>10</i>
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DATE MAILED: 05/12/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/851,628

Applicant(s)

Cohen et al.

Examiner

David S. Romeo 5/9/99

Group Art Unit

1646

☒ Responsive to communication(s) filed on 2-22-99

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-4, 6-10, 12-17, 24, 28, and 32 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-4, 6-10, 12-17, 24, 28, and 32 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. The amendment filed 02/22/99 (Paper No. 9) has been entered in full. Claims 1-4, 6-10, 12-17, 24, 28 and 32 are pending and are being examined.

2. Any objection or rejection of record that is not maintained in this Office action is
5 withdrawn.

3. The rejection of claim(s) 12 under 35 U.S.C. § 112, second paragraph, is maintained. Applicants argue that the human osteogenic and bone morphogenetic proteins were well known in the art. Applicants' arguments have been fully considered but they are not persuasive. The material elements upon which applicant relies (i.e., OP-1, OP-2, OP-3, and BMP2-6) are not
10 recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

4. The rejection of claim(s) 3 and 4 under 35 U.S.C. § 112, second paragraph, is maintained. Applicants argue that the meaning of "C-terminal cysteine domain" was well known in the art. Applicants' arguments have been fully considered but they are not persuasive. The claims recite
15 "a C-terminal cysteine domain" and it is unclear whether "the C-terminal seven cysteine domain" or some portion thereof is intended.

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5. The rejection of claim(s) 1-4, 6-10, 12-17, 24, 28 and 32 under 35 U.S.C. 103(a) as being unpatentable over Glassock et al. (V) and Brenner et al. (U) in view of Kuberasampath et al. (BB, cited by Applicants) is maintained. Applicants argue that there is no suggestion or motivation to combine the references, there is no reasonable expectation of success, and that the references do not teach all the claim limitations. Applicants' arguments have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Both Glassock et al. and Brenner et al. provide both a suggestion and motivation to administer anti-inflammatory therapy to a mammal in, or at risk of, chronic renal failure. See the last Office action at page 10-11. Glassock et al. also teaches that glomerular filtration rate is reduced because of infiltration of the capillaries by inflammatory cells (page 1295, column 2, paragraph 2). One of ordinary skill in the art would reasonably expect that suppressing inflammation would reduce the infiltration of the capillaries by inflammatory cells and glomerular filtration rate would increase, or that suppressing inflammation would cause a clinically significant improvement in a standard marker of renal function, wherein said standard marker is glomerular filtration rate. Kuberasampath et al. teach a method of immunosuppression with OP-1. One of ordinary skill in the art would have a reasonable expectation that immunosuppression with OP-1 would reduce the infiltration of the

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capillaries by inflammatory cells and glomerular filtration rate would increase. Claims 13, 14 and 15 do not require the treatment of the recited conditions. The claims only require administering OP-1 to a mammal in, or at risk of, chronic renal failure and improvement in a standard marker of chronic renal function, which the references provide. Brenner et al. teach that in the relatively early stages of CRF the GFR is reduced to levels of about 35-50% of normal, as recited in claim 24. One of ordinary skill in the art would have reasonable expectation that in the relatively early stages of CRF the number of functional nephron units is less than about 50% of normal (claim 17). Also with regards to claims 17 and 24 and with regards to claims 28 and 32, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable parameters by routine experimentation.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David S. Romeo whose telephone number is (703) 305-4050. The examiner can normally be reached on Monday through Friday from 6:45 a.m. to 3:15 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242.

10 Faxed draft or informal communications should be directed to the examiner at (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmer

ELIZABETH C. KEMMER
PRIMARY EXAMINER

SLR
May 9, 1999